REMARKS

In the Action, claims 1, 2, 4-7, 9-29, 31 and 41-43 are rejected. In response, claim 14 is amended.

Claim 14 is amended to recite growth inhibitor proteins to remove the term "proteinogenic" which is objected to in the Action. Growth factors are known to be proteins, and thus, the term "proteinogenic". However, to advance this application, claim 14 is amended to refer to the growth factor protein, thereby removing the term considered objectionable by the Examiner. This amendment is submitted to obviate the rejection under 35 U.S.C. § 112, first paragraph.

In view of these amendments and the following comments, reconsideration and allowance are requested.

The Rejections

On page 8 of the Action, claims 17 and 20 are rejected under 35 U.S.C. § 103(a) as being obvious over DE 199 39 403 to Schnabelrauch et al. Applicants note that the remaining claims are not listed in the rejection, although certain claims are discussed in the paragraphs following the rejection. Thus, the rejection does not clearly identify the claims in the rejection.

To the extent the Action intended to refer to claim 1, Applicants submit that independent claim 1 is not obvious over DE '403. DE '403 does not disclose or suggest a porous bioabsorbable inorganic filler or a porous calcium phosphate having the features recited in claim 1. DE '403 teaches that the pores develop after reabsorption of the inorganic filler under *in vivo* conditions.

Enclosed is a Declaration Under 37 C.F.R. § 1.132 by the inventor. The Declaration addresses the rejections and DE '403 as interpreted by one of ordinary skill in the art. This Declaration is submitted as evidence of the non-obviousness of the claimed invention.

Claim 1 specifically recites a calcium phosphate having a pore volume accessible to the polymerization initiator of 0.4 cm^3/g or more and having a specifically defined pore diameter, particle size and BET surface area. DE '403 does not disclose or suggest these features. DE '403 does not disclose a polymerization initiator and/or polymerization activator being drawn into the pore system as disclosed on page 17 of the present specification.

DE '403 discloses "coating" the inorganic filler but does not disclose or suggest the claimed method of producing a self-hardening bioabsorbable composite material. DE '403 does not disclose the specific calcium phosphate as claimed. The Action refers generally to DE '403 disclosing calcium phosphate generally. DE '403 is silent regard the properties or characteristics of the calcium phosphate or other inorganic materials and clearly fails to disclose a porous calcium phosphate as in the claimed invention. The behavior of the resulting cement is strongly dependent on the filler. One skilled in the art would have no reasonable expectation that a porous material would be effective, particularly in view of the known and widely recognized disadvantages of porous filters.

Contrary to the suggestion in the Action, DE '403 does not disclose a porous filler. DE '403 refers only to bioabsorbable inorganic fillers with calcium carbonate being preferred. DE '403 also specifically discloses that the surface of the filler material is coated "by conventional methods". There is no suggestion that the polymerization initiator or polymerization activator is retained in the pores of a porous filler material.

The Action does not provide an adequate factual basis or reasonable rationale to support the assertion that the claimed calcium phosphate would have been obvious to one of ordinary skill in the art based on the disclosure of DE '403. DE '403 does not disclose calcium phosphate having a pore volume that is accessible to a polymerization initiator and/or polymerization activator. DE '403 refers only to coating the particles. One skilled in the art would not reasonable interpret the broad general reference to "inorganic fillers" as satisfying the claimed requirements of the calcium phosphate having a pore volume of 0.4 cm^3/g or more, pore diameters of diameters of 0.1 to 500 μm and/or particles of 1 to 500 μm and/or a BET surface area of at least 0.1 m^2/g as recited in claim 1. The Action does not address these aspects of claim 1 and fails to provide any rational basis to support the conclusion that these features would have been obvious to one skilled in the art. Accordingly, Applicants respectfully submit that the Action has not established prima facie obviousness of independent claim 1.

The present invention is based on Applicants discovery that porous materials used in a fully bioabsorbable composition have advantages over the non-porous materials such as those conventionally used in DE '403. The porous materials of the present invention enable the growth of cells into the cavities of the material which result in better adhesion and anchoring of bone cells and provide a direct bonding between the bone tissue and the bioabsorbable composite material at the interface without the formation of an interlayer of connective tissue. The porous materials of the present invention exhibit a faster integration into the bone tissue.

The porous biodegradable materials of the claimed invention contain an *in situ* hardening polymer and a resorbable bioinorganic filler that has a faster rate of biodegradation due to the large surface area of the materials. The pores of the resorbable bioinorganic filler are accessible to degrading media such as water, dissolved salts and enzymes, thus enabling the bone

regeneration material to be resorbed faster. The porosity of the claimed filler material is an important aspect of the invention to improve and accelerate the biodegradation of the bioabsorbable composite material as a result of the polymers generated by the *in situ* hardening of the polymerizable monomers.

As disclosed on page 3, lines 3 and 4 of DE '403, the pore system of DE '403 is created by the *in vivo* conditions by the resorption of the inorganic filler while conserving the crosslinked matrix. Thus, the pores in DE '403 are formed in the polymer matrix by the resorption of the inorganic material and not by the porosity of the inorganic material from which the composition is made. DE '403 does not disclose or suggest a porous calcium phosphate and does not disclose calcium phosphate having a pore volume of 0.4 cm^3/g or more as claimed. One skilled in the art in reviewing DE '403 would conclude that the fillers are not porous and only by the degradation of the inorganic filler do the pores develop in the resulting polymer matrix of DE '403.

The Action does not provide sufficient evidence to support the assertion that the filler of DE '403 is porous or that it would have been obvious to one of ordinary skill in the art to use a porous filler based on the disclosure of DE '403. In view of the above, independent claim 1 is not obvious over DE '403.

The dependent claims are also not obvious for reciting additional features of the invention that are not disclosed or suggested in combination with DE '403. For example, DE '403 does not disclose the modifying constituents of claim 2, the viscosity adjusting component of claims 4-6, one of the components reacting in water to form a water-soluble product as in claim 7, the use of sodium hydrogen carbonate as a pH modifying agent and pore-forming substance as in claim 9, one of the constituents acting as an adhesion-imparting agent of claim

10, the polymerization initiator mixed with the bone regeneration material in an amount of 0.1 to 20% by weight as in claim 18, the polymerization initiator being an organic peroxide as in claim 19, the amount of the polymerization initiator of claim 21, the specific polymerization activators of claim 22, or drawing the polymerization activator into the bone regeneration material as in claim 23, in combination with the features of claim 1. As noted above, DE '403 discloses coating the particles and does not disclose or suggest the polymerization activator being absorbed into a porous particle. DE '403 specifically discloses a coated particle, and thus, does not disclose removing the excess amount of the polymerization activator as specifically recited in claim 23.

DE '403 also does not disclose the inorganic bone regeneration materials of claim 24, immobilizing the polymerization initiator in the bone regeneration material as in claims 25 and 26, the pore volume of the calcium phosphate of claim 28, the specifically defined calcium phosphate of claim 29, or the monomers of claim 31, either alone or in combination with the features of claim 1.

Claims 17 and 20 are also not obvious over DE '403. DE '403 does not disclose a solution of the polymerization initiator where the solution is allowed to infiltrate the bone regeneration material and drying the bone regeneration material as in claim 27, or forming a melt or solution of the polymerization activator added to the regeneration material to infiltrate the bone regeneration material, and drying the bone regeneration material as in claim 20, in combination with the features of claim 1.

In view of the above comments, the claims are not obvious over DE '403.

On page 12 of the Action, claims 12-14, 16, 24, 27 and 28 are rejected under 35 U.S.C. § 103(a) as being obvious over DE '403, and further in view of U.S. Patent No. 4,373,217 to

Draenert. These claims are submitted as being allowable as depending from an allowable base claim and for reciting additional features of the invention. Draenert does not specifically disclose a colorant or contrasting agent as in claim 12, a pharmaceutically active ingredient as in claim 13, the active ingredient being antibiotics, anti-inflammatories, growth factors and/or cancerostatics as in claim 14, in combination with the method steps of claim 1.

Draenert also does not disclose the bone regeneration material in the form of powder or granules as in claim 16, the inorganic materials of claim 24, the properties of the calcium phosphate of claim 27, or the properties of the calcium phosphate of claim 28, in combination with the method steps of claim 1.

Draenert is cited for disclosing calcium phosphate as a filler material. Moreover, Draenert discloses the calcium phosphate having a large pore volume in the order of 0.3 to 0.5 ml/g. These calcium phosphates are normally relatively soft as disclosed in column 3, lines 50-52, and exhibit numerous disadvantages as disclosed in column 3, line 58, to column 4, line 12. Curing of the cement is not ensured due to incomplete polymerization of the acrylate or methacrylate monomers. As a result, there is a risk that the relatively large proportion of residual acrylate and methacrylate monomer will remain after curing which can enter the patient's circulatory system. DE '403 and Draenert both use a non-porous bioabsorbable filler to avoid these problems.

Draenert does not disclose the claimed porous calcium phosphate as suggested in the Action. Draenert specifically uses a calcium phosphate having a pore volume below 0.1 ml/g, and preferably below 0.05 ml/g, and thus, avoids the use of the porous calcium phosphate. The pore volume of Draenert is obtained by precipitating tricalcium phosphate as a starting material having a pore volume of 0.35 ml/g and 0.4 ml/g. See, for example, Example 3A in column 4,

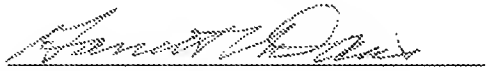
lines 44-60. The tricalcium phosphate starting materials are annealed at elevated temperatures. Draenert discloses mixing the annealed starting materials having a pore volume below 0.1 ml/g with the polymerizable monomers. In Example 1, Draenert discloses filling the pores of the porous calcium phosphate with glycerin, thereby reducing the pore volume to less than 0.1 ml/g.

In view of the above, Draenert clearly fails to disclose or suggest the claimed method or the claimed calcium phosphate having a pore volume of 0.4 cm^3/g or more. Draenert is silent regarding a calcium phosphate as defined in the claimed invention. Furthermore, Draenert specifically teaches away from the claimed calcium phosphate and discloses the use of a pretreated tricalcium phosphate having a pore volume of less than 0.1 ml/g.

Draenert further relates to a bone cement that is not resorbed by the body. One skilled in the art would recognize that the Draenert product does not suggest the claimed bioabsorbable composite material. Draenert is directed to an implantation material that has an opposite mode of action to that of the claimed invention. Thus, Draenert is unrelated to DE '403 and is unrelated to the claimed invention. Accordingly, the claims are not obvious to one skilled in the art either standing alone or in combination with DE '403.

In view of the above comments, the claims are submitted as being allowable over the art of record. Accordingly, reconsideration and allowance are requested.

Respectfully submitted,



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